

REMARKS

A. Status of the Claims

Claims 1-11, 31-41 and 64-69 were examined. Claims 1, 31, 64, 65, 66, and 69 have been amended. No claims have been canceled. Claims 70-91 have been added. Thus, claims 1-11, 31-41 and 64-91 will be pending upon entry of the amendments.

B. The Claim Objections Are Overcome

Applicant amended claims 65, 66 and 69 such that claims 65-69 depend from claim 64 instead of claim 1. This corrects Applicant's inadvertent error, and overcomes the objection.

C. The Pending Claims Are Novel over Kontos

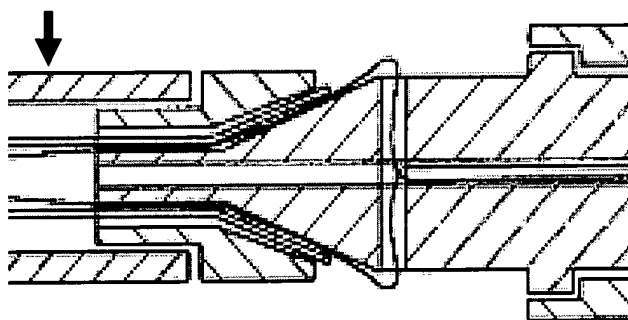
Each of the independent claims has been amended to delete the unnecessary language that the lumen is adapted to receive a length of suture, and to add the language "length of" where appropriate.

1. Independent Claim 1

Independent claim 1 is directed to a medical device that comprises, in relevant part, a body, a first needle guide channel extending from a first needle guide channel opening formed in the body to a second needle guide channel opening formed in the body; and a needle connected to a length of suture and backloaded into the first needle guide channel. The claim has been amended to recite that the medical device is configured such that the first needle guide channel opening and the second needle guide channel opening will be directly exposed to a patient's tissue when the medical device is used during a procedure. This amendment was made for the sole purpose of distinguishing Kontos.

Only one of the needle guide channel openings that define a given needle guide channel of the Kontos device will be directly exposed to a patient's tissue when the device is used during

a procedure. The other, more distal such opening is not directly exposed due to the existence of the structure to which the arrow below points:



For at least this reason, claim 1 and its dependent claims are novel over Kontos, and the rejection should be withdrawn. Furthermore, nothing in Kontos suggests a device that is configured as recited in claim 1.

2. Independent Claim 31

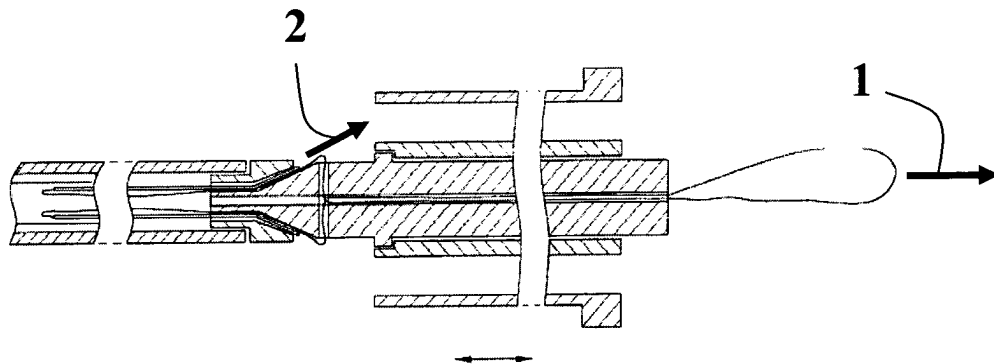
Independent claim 31 is directed to a medical device comprising, in relevant part, a body; a first needle guide channel extending from a first needle guide channel opening formed in the body; and a needle connected to a length of suture and backloaded into the first needle guide channel. The suture is threaded through the lumen such that when the length of suture is pulled in a first direction away from the body, the needle is advanced out of the first needle guide channel in a second direction. The first direction has a positive longitudinal component and the second direction having a negative longitudinal component. The underlined portions of claim 31 was added by amendment for the sole purpose of distinguishing Kontos.

The Office states:

With regards to the positive and negative longitudinal components, the device of Kontos will inherently have a positive or negative longitudinal component since determining the component is merely dependent upon the spatial relationship is determined by the user. Therefore, the recited limitation of the longitudinal components is merely a relative limitation.

Office Action at p. 3. This statement is incorrect.

The recited limitations of positive and negative longitudinal components are relative to **each other**, not to **the user** as the Office seems to assert. Kontos does not disclose or suggest a length of suture threaded through a lumen such that when the length of suture is pulled in a first direction away from the body, the needle is advanced out of the first needle guide channel in a second direction, the first direction having a positive longitudinal component and the second direction having a negative longitudinal component. Instead, if the suture in Kontos is pulled in a first direction away from the body of Kontos (as shown by arrow 1 below), the needle will be advanced in a second direction as shown by arrow 2 below, but the two directions **will not** have positive and negative longitudinal components (they both have positive longitudinal components):



As a result, Kontos does not anticipate claim 31, and rejection of claim 31 and its dependent claims should be withdrawn. Furthermore, nothing in Kontos suggests a device that is configured as recited in claim 31.

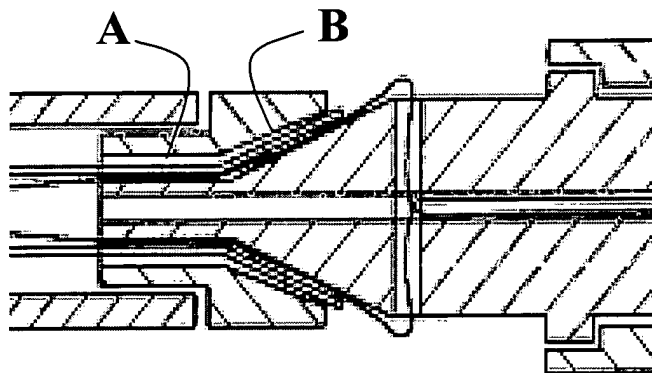
3. Independent Claim 64

Independent claim 64 has been amended for the sole purpose of distinguishing Kontos, and now recites that the medical device is configured such that the first needle guide channel opening and the second needle guide channel opening will be directly exposed to a patient's

tissue when the medical device is used during a procedure. This claim and its dependent claims are novel over Kontos for the same reason as independent claim 1 and its dependent claims. Accordingly, the rejection should be withdrawn.

4. Dependent Claims 2, 32 and 65

The Office asserts that these claims are anticipated by Kontos because the needle guide channel shown in Kontos FIG. 54 is arcuate shaped. That is not correct. The FIG. 54 needle guide channels have two portions (labeled A and B below for one of the channels): both are straight portions, and one is at an angle to the other. The two portions meet at a hard angle:



As this figure shows, the channels are not arcuate shaped, and the rejection of these dependent claims should be withdrawn for this additional reason.

5. Dependent Claims 5, 35 and 68

The Office asserts that these claims are anticipated by Kontos because “Kontos teaches the device as being flexible for all embodiments.” These claims recite that the claimed connector piece is bendable “such that it can be fixed in a variety of positions.” Nothing in Kontos teaches or suggests that the FIG. 54 structure asserted by the Office to qualify as the claimed connector piece is bendable such that it can be fixed in a variety of positions. The rejection of these dependent claims should be withdrawn for this additional reason.

7. Dependent Claims 8, 9, 38 and 39

Dependent claims 8 and 38 recite that one of the one or more additional needle guide channels are arcuate shaped. Dependent claims 9 and 39 recite that each of the one or more additional needle guide channels are arcuate shaped. These four dependent claims are patentable over Kontos for the same additional reason provided above with respect to dependent claims 2, 32 and 65.

D. The New Claims Are Patentable over Kontos

1. New Independent Claim 70

New independent claim 70 is directed to a medical device that comprises a body; a lumen extending from a first lumen opening formed in the body to a second lumen opening formed in the body; a first needle guide channel extending from a first needle guide channel opening formed in the body to a second needle guide channel opening formed in the body; and a needle connected to a length of suture and backloaded into the first needle guide channel. The length of suture being threaded through the lumen such that the needle will advance **in a forward direction** out of the first needle guide channel when the length of suture is pulled **in a rearward direction**.

The needles in Kontos can only advance in a rearward direction when the length of suture in Kontos is pulled in a rearward direction. The Kontos device is not configured to allow the needles to advance in a forward direction when the length of suture is pulled in a rearward direction. For at least this reason, new independent claim 70 and its dependent claims are patentable over Kontos.

2. New Independent Claim 81

New independent claim 81 is directed to a medical device that comprises a body; a lumen extending from a first lumen opening formed in the body to a second lumen opening formed in the body; a first needle guide channel extending from a first needle guide channel opening formed in the body to a second needle guide channel opening formed in the body; a first needle connected to a first length of suture and backloaded into the first needle guide channel, the first length of suture being threaded through the lumen such that the needle will be advanced out of the first needle guide channel by pulling on the length of suture; a second needle guide channel extending from a third needle guide channel opening formed in the body to a fourth needle guide channel opening formed in the body; and a second needle connected to a second length of suture and backloaded into the first needle guide channel, the second length of suture **being separate from** the first length of suture, and the second suture being threaded through the lumen such that the needle will be advanced out of the first needle guide channel by pulling on the second length of suture.

The Kontos device is operated using one length of suture, not two separate lengths of suture as recited in new independent claim 81. For at least this reason, new independent claim 81 and its dependent claims are patentable over Kontos.

E. Petition for Extension of Time in this and Future Responses

Pursuant to 37 C.F.R. § 1.136(a), Applicant petitions for a one-month extension of time. If the check is omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included, the Office is authorized to deduct or credit the appropriate fees from or to Fulbright & Jaworski Deposit Account No.: 50-1212/AFEI:002US.

The Office is further authorized to treat any concurrent or future reply that requires a petition for an extension of time under 37 C.F.R. § 1.136(a) to be timely as incorporating a petition for an extension of time for the appropriate length of time, and to deduct all required fees under 37 C.F.R. §§ 1.16 to 1.21 relating to any such replies of other relevant papers from Fulbright & Jaworski Deposit Account No.: 50-1212/AFEI:002US.

F. Conclusion

Applicant respectfully submit that claims 1-11, 31-41 and 64-91 are in condition for allowance. The Office is invited to contact the undersigned attorney at (512) 536-3031 with any questions.

Respectfully submitted,



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